February 5, 2021

Acuitive Technologies, Inc.
% Robert Poggie
President
BioVera, Inc
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, QC J7V7P2
Canada

Re: K203334
Trade/Device Name: The Acuitive Citrefix™ Knotless Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: January 6, 2021
Received: January 7, 2021

Dear Robert Poggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2023 *See PRA Statement below*

510(k) Number *(if known)*

K203334

Device Name

The Acuitive CITREFIX™ Knotless Suture Anchor

Indications for Use *(Describe)*

The Acuitive CITREFIX™ Knotless Suture Anchor is intended for fixation of suture to bone in the shoulder foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY – CITREFIX™ Knotless Suture Anchor

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of the CITREFIX Knotless Suture Anchor.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint Louis, Notre-Dame-de-L'Ile-Perrot, QC J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone & Fax Number:	514-901-0796
Date of Submission:	January 6, 2021

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Acuitive Technologies, Inc.
Manufacturer Address:	50 Commerce Drive, Allendale, NJ 07401, USA
Registration Number:	TBD
Contact Name:	Matthew Poggie
Title:	Sr. VP R&D Operations
Device Trade Name:	The Acuitive CITREFIX™ Knotless Suture Anchor
Device Common Name:	Bone Anchor, Suture Anchor
Classification Name:	Single/multiple component metallic bone fixation appliances an accessories (21 C.F.R. § 888.3030), and Smooth or threaded metallic bone fixation fastener (21 C.F.R. § 888.3040)
Classification Code:	MAI and MBI
Classification Panel:	Orthopedic
Regulation Numbers:	21 C.F.R. § 888.3030 and 888.3040

C1. PRIMARY PREDICATE DEVICE

K051219	Arthrex PushLock suture anchor

C2. REFERENCE DEVICE

K200725	CITREGEN™ Tendon Interference Screw (TIS), CITRELOCK™ Tendon Fixation Device

D. Indications for Use

The Acuitive CITREFIX Knotless Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

E. Device Description

The CITREFIX Knotless Suture Anchor is comprised primarily of Acuitive Technologies' proprietary CITREGEN, citrate-based polymer / bioceramic composite material. An integral eyelet made of PEEK conforming to ASTM F2026 facilitates passage of the suture through the tip of the anchor. The CITREFIX device is offered in diameters between 2.9 and 5.5 mm and lengths ranging between 12.5 and 24.0 mm. The CITREFIX Knotless Suture Anchor is implanted with reusable instruments, which include size specific drill and awl options for preparing the bone and an insertion instrument for placement of the CITREFIX device. Suture is not provided with the CITREFIX device.

The CITREFIX Knotless Suture Anchor is made from CITREGEN biomaterial, a homogeneous biocomposite of 60 % unsintered hydroxyapatite (HA) and 40 % polyester. CITREGEN's polymer component is a citrate-based network of completely amorphous polymer chains crosslinked together to form an elastomeric material. As water penetrates the subject device, surface erosion of the polymer occurs through hydrolysis of ester bonds located between the monomers and at crosslink sites.

F. Comparison of Technological Characteristics

The CITREFIX Knotless Suture Anchor has the similar intended and indications for use, as well as similar technological characteristics and principles of operation as the predicate device, and is comprised of the same CITREGEN resorbable biomaterial as the reference device (K200725). The subject Acuitive and predicate Arthrex suture anchors have similar technological characteristics that include:

- Primarily composed of resorbable biocomposite materials,
- PEEK eyelet to facilitate suture fixation to bone,
- Direct-insertion, interference fixation (push-in design),
- Clinical indications and intended use,
- Surgical technique,
- Similar drill and awl instrument options for preparing the bone, and
- Provided sterile to the end user.

The subject device is comprised of CITREGEN biomaterial, which is a homogeneous biocomposite comprised of unsintered hydroxyapatite (HA) and polyester that is bioresorbed over time in vivo. The predicate Arthrex device is comprised of BioComposite material that is comprised of biphasic calcium phosphate and PLDLA that also resorbs in vivo. The material differences between the Acuitive device and the predicate are the polyester, bioceramic, and weight percentage of bioceramic. The specific materials used differ from the predicate but do not raise different issues of safety or effectiveness.

The minor technological differences between the subject Acuitive CITREFIX and predicate Arthrex PushLock devices do not raise new issues of safety or effectiveness. The data demonstrates that the CITREFIX is substantially equivalent to the predicate device.

G. Performance Data

The performance characteristics of CITREFIX Knotless Suture Anchors were established via studies of functional performance in vitro, packaging, shelf life testing, sterility including EO residuals, physical and chemical properties per ASTM F2902 and biocompatibility per ISO 10993-1. Packaging and shelf life tests using real and accelerated time aging were performed with passing results. The labeled shelf-life of the product is one year based on the stability data analyzed to date. Bacterial endotoxin testing showed CITREFIX to meet the set endotoxin limits (<20 EUs / surgical procedure). Biocompatibility of CITREFIX devices was demonstrated by ISO 10993 testing for a permanent implant, including toxicological risk assessment through the lifecycle of the device.

Evaluation of performance characteristics of the CITREFIX device was guided by the FDA guidance document “Premarket Notification (510(k)) Submissions for Bone Anchors” issued on January 3, 2017, pre-submission Q170251, and ASTM standards F2502, F2902, and F1635. Bench testing was performed on the worst-case, smallest diameter Citrefix device (2.9mm diameter), intermediate size (4.5mm) subject CITREFIX device and same-size predicate Arthrex PushLock device for pull-out testing at time-zero, following a period soaking in 37C PBS and after 5,000 cycles of simulated physiological loading, with results demonstrating substantial equivalence of the predicate and subject devices.

Biocompatibility studies performed with CITREGEN devices at various stages of life cycle through 90% demonstrated biocompatibility per ISO 10993-6. Extractables & leachables (E&L) testing at various stages of test article life cycle was performed, with biocompatibility and toxicological risk assessments concluding that CITREGEN material devices are safe for long-term implantation.

H. Conclusion

Based on the similarities of indications for use, technological characteristics, and summary of data, Acuitive Technologies has determined that the subject device, the CITREFIX Knotless Suture Anchor, is substantially equivalent to the currently marketed predicate device, the Arthrex PushLock suture anchor. Performance testing and assessment of biocompatibility has demonstrated that the device functions as intended without raising new questions of safety or effectiveness.